



Attorney Docket No. RADO-001/02US

PATENT

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By: Cathi L.G. Thoorsell  
Cathi L.G. Thoorsell

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of Mark D. BEDNARSKI *et al.*

Serial No.: 10/681,855 Examiner: Not yet assigned

Confirmation No.: 7135 Art Unit: 1614

Filed: October 7, 2003

For: **X-NITRO COMPOUNDS, PHARMACEUTICAL COMPOSITIONS  
THEREOF AND USES THEREOF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT TRANSMITTAL**

Enclosed is an Information Disclosure Statement and accompanying Form PTO/SB/08A for the above-identified patent application. In accordance with 37 C.F.R. §1.97(b), no additional fee for submission of the IDS is required. A return receipt postcard is also enclosed.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 03-3117.

Dated: April 8, 2004

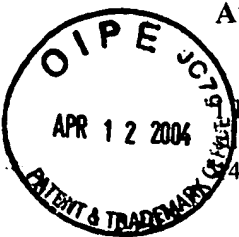
Cooley Godward LLP  
ATTN: Patent Group  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306-2155  
Tel: (650) 843-5000 Fax: (650) 857-0663  
672394 v1/PA

Respectfully submitted,  
COOLEY GODWARD LLP

By: Sunil K. Singh  
Sunil K. Singh  
Reg. No. 45,298

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**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97(b)**

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant(s) hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. Pursuant to 37 C.F.R. §1.98, a copy of each document cited in the attached Form PTO/SB/08 is enclosed. This Information Disclosure Statement is filed before the mailing date of a first office action on the merits.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08A to the undersigned.

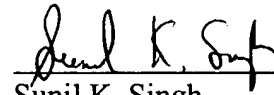
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Cooley Godward LLP  
ATTN: Patent Group  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306-2155  
Tel: (650) 843-5000  
Fax: (650) 857-0663

672395 v1/PA

Respectfully submitted,  
**COOLEY GODWARD LLP**

By:

A handwritten signature in black ink, appearing to read "Sunil K. Singh", is written over a horizontal line.

Sunil K. Singh  
Reg. No. 45,298

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)



Substitute for form I449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<i>Complete if Known</i>	
				<b>Application Number</b>	10/681,855
				<b>Filing Date</b>	October 7, 2003
				<b>First Named Inventor</b>	Mark D. BEDNARSKI
				<b>Group Art Unit</b>	1614
				<b>Examiner Name</b>	not yet assigned
<b>Sheet</b>	1	<b>of</b>	3	<b>Attorney Docket Number</b>	RADO-001/02US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	(if known)		
	P1	5,970,974		Van Der Linden, Klaus	10-26-1999
	P2	5,954,047		Armer, Thomas Alex	09-21-1999
	P3	5,950,619		van der Linden, Klaus	09-14-1999
	P4	5,698,155		Grosswald, Ralph R.	12-16-1997
	P5	5,579,458		Yokosuka, Hirobumi	11-26-1996
	P6	5,556,611		Biesalski, Hans K	09-17-1996
	P7	5,112,598		Biesalski, Hans K.	05-12-1992
	P8	4,765,539		Noakes, Timothy J.	08-23-1988
	P9	3,916,899		Theeuwes, Felix	11-04-1975
	P10	3,845,770		Theeuwes, Felix	11-05-1974

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office <sup>3</sup> Code <sup>5</sup>	Number <sup>4</sup>	Kind (if known)			

<b>Examiner Signature</b>		<b>Date Considered</b>	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.

<sup>2</sup> See attached Kinds of U.S. Patent Documents.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08A (08-00)

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	10/681,855
				Filing Date	10/07/2003
				First Named Inventor	Mark D. BEDNARSKI
				Group Art Unit	1614
				Examiner Name	Not yet assigned.
Sheet	2	Of	3	Attorney Docket Number	RADO-001/02US

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	D1	ALDERMAN, A. "A Review of Cellulose Ethers in Hydrophilic Matrices for Oral Controlled-Release Dosage Forms," <i>Int. J. Pharm. Tech &amp; Prod. Mfr.</i> (1984) 5(3) 1-9.		
	D2	ARMSTRONG <i>et al.</i> , "Role of Glutathione Depletion and Reactive Oxygen Species Generation in Apoptotic Signaling in a Human B Lymphoma cell line," <i>Cell Death Differ.</i> (2002) 9(3); 252-263.		
	D3	BAMBA <i>et al.</i> , "Release Mechanisms In Gelforming Sustained Release Preparation," <i>Int. J. Pharm.</i> (1979), 2, 307.		
	D4	BERGE <i>et al.</i> , "Pharmaceutical Salts," <i>J. Pharm. Sci.</i> (1977) 66:1-19.		
	D5	BROWN <i>et al.</i> Tirapazamine: Laboratory Data Relevant to Clinical Activity Anti-cancer Drug Design (1998), 13, 529-539.		
	D6	DURING <i>et al.</i> "Controlled Release of Dopamine from a Polymeric Brain Implant: In Vivo Characterization," <i>Ann. Neurol.</i> (1989) 25:351.		
	D7	HOWARD <i>et al.</i> , "Intracerebral Drug Delivery in Rats with Lesion-induced Memory Deficits," <i>J. Neurosurg.</i> (1989) 71:105.		
	D8	LANGER (1990) "New Methods of Drug Delivery," <i>Science</i> 249: 1527-1533		
	D9	LANGER "Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: a Review" <i>JMS-Rev. Macromol. Chem. Phys</i> (1983) C23(1), 61-126.		
	D10	LEVY <i>et al.</i> , "Inhibition of Calcification of Bioprosthetic Heart Valves by Local Controlled-Release Diphosphonate," <i>Science</i> (1985) 228:190-196.		
	D11	NING <i>et al.</i> "The Antiangiogenic Agents SU5416 and SU 6668 Increase the Antitumor Effects of Fractionated Irradiation," <i>Radiat. Res.</i> (2002) 157(1): 45-51.		
	D12	ROSENTHAL <i>et al.</i> , "A Phase I Single-Dose Trial of Gadolinium Texaphyrin (Gd-Tex), a Tumor Selective Radiation Sensitizer Detectable by Magnetic Resonance Imaging," <i>Clin. Cancer Res.</i> , (1999), 739-745.		
	D13	RUPNOW <i>et al.</i> , "p53 Mediates Apoptosis Induced by c-Myc Activation in Hypoxic or Gamma Irradiated Fibroblasts," <i>Cell Death Differ.</i> (1998) 5(2): 141-147.		

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	10/681,855
				Filing Date	10/07/2003
				First Named Inventor	Mark D. BEDNARSKI
				Group Art Unit	1614
				Examiner Name	Not yet assigned.
Sheet	3	Of	3	Attorney Docket Number	RADO-001/02US

	D14	SAUDEK <i>et al.</i> , " <u>A Preliminary Trial of the Programmable Implantable Medication System for Insulin Delivery</u> ," <i>N. Engl. J. Med.</i> (1989) 321:574-579.	
	D15	SEFTON, " <u>Implantable Pumps</u> ," <i>CRC Crit. Ref. Biomed. Eng.</i> (1987) 14:201-240.	
	D16	STRATFORD <i>et al.</i> <u>Bioreductive Drugs into the Next Millennium</u> <i>Anti-Cancer Drug Design</i> (1998), 13, 519-528.	
	D17	TREAT <i>et al.</i> , " <u>Liposomes in the Therapy of Infectious Disease and Cancer</u> " Lopez-Berestein and Fidler (eds.), Liss, New York (1989), pp. 353-365.	
	D18	VERMA <i>et al.</i> , " <u>Osmotically Controlled Oral Drug Delivery</u> " <i>Drug Dev. Ind. Pharm.</i> , (2000), 26:695-708.	
	D19	VERSCOYLE <i>et al.</i> , " <u>Pharmacokinetics of Isotretinoin (ISO) in Rats Following Oral Dosing or Aerosol Inhalation</u> ," <i>British J. Cancer</i> , 1999, 80, Suppl. 2, 96.	
	D20	WILSON, <i>et al.</i> <u>Radiation-activated Prodrugs as Hypoxia-selective Cytotoxins: Model Studies with Nitroaryl methyl Quaternary Salts</u> <i>Anti-cancer Drug Design</i> (1998) 13, 663-685.	
	D21	YAMAGUCHI <i>et al.</i> <u>Protodynamic Therapy with Motexafin Lutetium (Lu-Tex) Reduces Experimental Graft Coronary Artery Disease Transplantation</u> (2001) June 15:71(11) 1526-32.	

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number.

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